NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRIAN FELDMAN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. SCYNEXIS, INC, DAVID ANGULO, and IVOR MACLEOD, Defendants.	Case No. 2:23-cv-22082 (BRM) (CLW) **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before the Court is a Motion to Dismiss pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6) filed by Defendants Scynexis, Inc. ("Scynexis"), David Angulo ("Angulo"), and Ivor Macleod ("Macleod") (collectively, "Defendants") (ECF No. 28). Lead Plaintiff[1] Brian Feldman, individually and on behalf of all others similarly situated ("Plaintiff") filed an Opposition (ECF No. 29), and Defendants filed a Reply (ECF No. 30). Having reviewed and considered the submissions filed in connection with Defendants' Motion and having declined to hold oral argument pursuant to Federal Rule of Civil Procedure 78(b), for the reasons set forth below and for good cause having been shown, Defendants' Motions to Dismiss (ECF No. 28) is **GRANTED**.

[1] On July 7, 2024, the Court issued an Order appointing lead plaintiff and approving lead counsel and liaison counsel, pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA") and 15 U.S.C. §78u-4 (1997). (ECF No. 11.)

I. BACKGROUND

A. Factual Background

For the purpose of this Motion to Dismiss, the Court accepts the factual allegations in the Amended Complaint as true and draws all inferences in the light most favorable to Plaintiffs. *See Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). The Court may also consider any "document *integral to or explicitly relied* upon in the complaint." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (quoting *Shaw v. Digit. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996)).

This suit is a putative class action arising out of alleged violations of the federal securities laws—specifically 15 U.S.C. §§ 78j(b) and 78t(a) (respectively, "Section 10(b)" and "Section 20(a)") of the Securities Exchange Act of 1934 (the "Exchange Act") and 17 C.F.R. § 240.10b-5 ("Rule 10b-5") promulgated thereunder by the Securities and Exchange Commission. (*See generally* ECF No. 14 ("Amended Complaint").) Scynexis is a biotechnology company primarily engaged in the development of ibrexafungerp, which is a broad-spectrum agent for fungal indications administered intravenously or orally. (*Id.* ¶ 2.) Scynexis's shares are listed on NASDAQ under ticker symbol SCYX. (*Id.* ¶ 18.) Scynexis is incorporated in Delaware and has its principal executive offices in New Jersey. (*Id.*) Angulo is the President and Chief Executive Officer ("CEO") and was also a Board of Directors member during the Class Period. (*Id.* ¶ 19.) Macleod is the Chief Financial Officer ("CFO") during the Class Period. (*Id.* ¶ 20.) Lead Plaintiff, Brian Feldman, and other plaintiffs are "putative class members consisting of persons and entities that purchased or otherwise acquired Scynexis securities between March 31, 2023, and September 22, 2023, inclusive (the 'Class Period')" and who have suffered significant losses and damages as a result of Defendants' alleged conduct. (*Id.* ¶¶ 1, 12, 17, 77, 90.) Plaintiff states all class members

were injured by purchasing Scynexis stock at artificially inflated prices during the Class Period. (*Id.* ¶¶ 52–54.)

"In June 2021, [Scynexis] received approval from the United States Food and Drug Administration ("FDA") for the use of ibrexafungerp tablets, distributed under the brand name BREXAFEMME® for the treatment of vulvovaginal candidiasis (also known as vaginal yeast infection)." (*Id.* ¶ 3.) The FDA promulgates Good Manufacturing Practice ("cGMP") regulations, which create "minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product that ensure a product is safe for use and has the ingredients and strength it claims to have." (*Id.* ¶ 4.) Beta-lactams, whether bacterial or non-bacterial, are a class of chemical compounds that can act as sensitizing agents in commercial drugs. (*Id.* ¶ 5.) Due to the risk of allergic reactions by the general public, "cGMP requires that the manufacture of non-antibacterial beta-lactam compounds are segregated from other compounds to reduce potential hypersensitivity reactions." (*Id.* ¶ 6.) Plaintiff states FDA regulations required Scynexis to build and maintain facility controls that would prevent cross-contamination of drug roducts. (Id. ¶ 26.) With regard to non-penicillin beta-lactams, "[t]he guidance states '[j]ust as [the] FDA considers the separation of production facilities for penicillins to be current good manufacturing practice, [the] FDA expects manufacturers to treat sensitizing non-penicillin beta-lactam-based products similarly.'" (*Id.* ¶ 29.) Likewise, Plaintiff claims Scynexis must prevent insanitary conditions pursuant to FDA guidance, which specifies the "[p]rocessing of beta-lactams that do not have a complete and comprehensive separation from non-beta-lactam products" as an example of an insanitary condition. (*Id.* ¶¶ 31–33.)

"According to the Company's fiscal 2021 annual report, by August 2021 the product had been manufactured, packaged, and distributed to pharmacies. Scynexis had agreements with

contract manufacturers and external vendors to produce the drug product and drug substance for ongoing clinical trials and for commercial product." (*Id.* ¶ 35.) At that time, Scynexis stated it had "[a] drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. We believe we have a team that is capable of managing these activities." (*Id.*) Scynexis further claimed the third-party vendors it had agreements with were able to "meet global and regulatory compliance requirements" and had the "required capabilities with respect to facilities, equipment and technical expertise." (*Id.*) However, the drug did not prove profitable for the company despite being its sole drug candidate and Scynexis decided to pivot away from BREXAFEMME. (*Id.* ¶ 36–37.)

As part of this pivot, Scyenxis found a commercialization partner, and "[o]n March 30, 2023, [Scynexis] entered into a license agreement with GSK plc ('GSK'), formerly known as GlaxoSmithKline, for an exclusive, royalty-bearing license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications." (*Id.* ¶ 7.) On June 21, 2023, under this agreement, Scynexis announced it had achieved a $25 million performance-based development milestone. (*Id.* ¶ 40.) On September 25, 2023, Scynexis reported that GSK had discovered potential cross-contamination of ibrexafungerp with a non-antibacterial beta-lactam drug substance, and, as a result, shortly thereafter declared it would conduct a recall of the product from the market and place a temporary hold on clinical studies of the drug until a mitigation strategy and resupply plan were determined. (*Id.* ¶¶ 8, 41.) After this announcement, Plaintiff claims Scynexis's "shares fell $1.13, or 34.14%, to close at $2.18 per share on September 25, 2023, on unusually heavy trading volume. The stock price continued to decline the next trading day by 11.47% to close at $1.93 per share on September 26,

2023, on unusually heavy trading volume." (*Id.* ¶¶ 9, 42.) On September 27, 2023, the company issued a press release announcing the voluntary nationwide recall of two lots of the drug, stating, "During a review of manufacturing equipment and cleaning activities at a supplier, SCYNEXIS was made aware of potential cross-contamination risk with a non-antibacterial beta-lactam drug substance." (*Id.* ¶ 43.) Scynexis reported in its 2023 third quarter report filed with the SEC that it had engaged with the FDA in September 2023 and "[the] FDA concurred with the Company's voluntary hold and placed a clinical hold on ibrexafungerp." (*Id.* ¶ 44.) "On January 1, 2024, the Company disclosed that it had agreed to revise the terms of license agreement with GSK because of the delays in commercialization and clinical development of BREXAFEMME caused by the recall and temporary hold on clinical studies" with the revision being a reduction in potential payments. (*Id.* ¶ 45.) In the annual report filed with the SEC on March 26, 2024, Scynexis stated it had engaged new manufacturers and vendors due to the possible beta-lactam cross contamination. (*Id.* ¶ 46.)

Plaintiff alleges:

> Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the equipment used to manufacture ibrexafungerp was not sufficiently separated from the manufacture of a non-antibacterial beta-lactam drug substance, presenting a risk of cross-contamination; (2) that the Company did not ensure compliance with current Good Manufacturing Practices ("cGMP"); and (3) that, due to the failure to ensure the manufacture of ibrexafungerp was separated from the manufacture of non-antibacterial beta-lactam drugs, there were undisclosed material risks to the Company's business, including risks related to potential recalls and delays in clinical studies.

(*Id.* ¶ 11.) As support for these claims, Plaintiff looks to industry analysts who "were surprised that clear FDA guidelines had not been followed" since one such analyst from Ladenburg

Thalmann wrote a report to shareholders in the months after the disclosure stating:

> We still lack clarity as to why the manufacturing equipment was shared with beta-lactams and how it was not discovered earlier. Recall, Brexafemme earned FDA approval for vulvovaginal yeast infections in June 2021, and we believe its commercial manufacturing is the same as its clinical manufacturer. We would expect that ahead of GSK's March licensing agreement it would have physically inspected the IBX manufacturing facilities.

(*Id.* ¶ 10.) Plaintiff also alleges "GSK was able to uncover within six months that the Company was not complying with cGMP and that a recall was needed." (*Id.* ¶ 62.)

Plaintiff states Angulo and Macleod, "because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market." (*Id.* ¶ 21.) Plaintiff also claims these Defendants "were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected," and correspondingly knew about adverse facts herein alleged, were aware of any concealment efforts, and had knowledge of the materially false and/or misleading statements Scynexis put out. (*Id.*)

B. Defendants' Alleged Misrepresentations and Omissions

Plaintiff alleges Defendants made a series of false and misleading statements and omitted material facts necessary to make the statements made not false or misleading: (1) regarding the equipment used to manufacture the drug not being sufficiently separated to prevent a risk of cross-contamination; (2) that Scynexis did not ensure compliance with applicable cGMP; and (3) that due to the failure to ensure proper separation to prevent cross-contamination in the manufacturing process of the drug, there were undisclosed material risks to Scynexis's business. (*See generally id.*)

1. Manufacturing and Supply of Ibrexafungerp

Plaintiff alleges in the Form 10-K filed by Scynexis for the period which ended December 31, 2022 (the "2022 10-K) and which was filed on the day the Class Period begins, Scynexis explicitly and falsely stated:

> A drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. We believe we have a team that is capable of managing these activities until GSK assumes responsibility for them pursuant to the License Agreement.
>
> The primary third-party vendors with which we have agreements in place to support manufacturing and supply both for clinical development and commercial needs have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements, satisfactory regulatory inspection history from relevant health authorities and proven track records in supplying drug substance and drug product for late-stage clinical and commercial use.

(*Id.* ¶ 47.)

Plaintiff alleges the "2022 10-K further purported to warn that the Company 'may' be held responsible for the contract manufacturers' failure to comply with cGMP and that the failure to comply with cGMP 'can' have legal implications" because it stated in relevant part:

> BREXAFEMME, ibrexafungerp, and any other future product candidates we may seek to develop will also be subject to ongoing regulatory requirements for the packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing. Practices (cGMP). As such, we and our contract manufacturers, which we will be responsible for overseeing and monitoring for compliance, are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time,

> money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The FDA may hold us responsible for any deficiencies or noncompliance of our contract manufacturers in relation to ibrexafungerp and any other future product candidates we may seek to develop. Failure to follow cGMP can result in products being deemed adulterated, which carries significant legal implications.

(*Id.* ¶ 48.)

Plaintiff states on May 1, 2023, Scynexis filed a Form ARS with the SEC, which reported Scynexis's Annual Report to security holders. (*Id.* ¶ 49.) Plaintiff claims the report had reiterated the statements from the 2022 10-K because it stated:

> We have agreements with external vendors that are capable of supplying drug substance and of producing drug product to support ongoing and planned clinical trials, as well as for commercial product.
>
> * * *
>
> A drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. We believe we have a team that is capable of managing these activities until GSK assumes responsibility for them pursuant to the License Agreement. The primary third-party vendors with which we have agreements in place to support manufacturing and supply both for clinical development and commercial needs have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements, satisfactory regulatory inspection history from relevant health authorities and proven track records in supplying drug substance and drug product for late-stage clinical and commercial use.

(*Id.*)

As in the 2022 10-K, Plaintiff states this Form ARS report had the same warning regarding the possibility of Scynexis being held responsible for contract manufactures' failure to comply with cGMP because it stated:

> BREXAFEMME, ibrexafungerp, and any other future product

> candidates we may seek to develop will also be subject to ongoing regulatory requirements for the packaging, storage, advertising, promotion, record-keeping and submission of safety and other postmarket information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (cGMP). As such, we and our contract manufacturers, which we will be responsible for overseeing and monitoring for compliance, are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The FDA may hold us responsible for any deficiencies or noncompliance of our contract manufacturers in relation to ibrexafungerp and any other future product candidates we may seek to develop. Failure to follow cGMP can result in products being deemed adulterated, which carries significant legal implications.

(*Id*.)

Plaintiff contends the above statements were materially false and misleading and failed to disclose material adverse facts about Scynexis's business, operations, and prospects. (*Id.* ¶ 51.)

C. Scienter Allegations

Plaintiff alleges Defendants acted with scienter because: (1) they knew that the public documents and statements issued in the name of Scynexis were materially false and misleading; (2) knew that such statements or documents would be disseminated to the investing public; and (3) knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. (*Id.* ¶ 55.) Plaintiff claims Angulo and Macleod had scienter "by virtue of their receipt of information reflecting the true facts regarding Scynexis, their control over, and/or receipt and/or modification of Scynexis's allegedly materially misleading misstatements and/or their associations with Scynexis which made them privy to confidential proprietary information concerning Scynexis, participated in the

fraudulent scheme alleged here." (*Id.* ¶ 56.)

Plaintiff states as support for the scienter allegations the contention that Scynexis's compliance with FDA guidelines was central to its business because it is "an extremely small company" with "only 36 full-time employees," and ibrexafungerp was its sole drug candidate. (*Id.* ¶ 57.) Plaintiff goes on to claim Scynexis's "primary business was the commercialization of ibrexafungerp, and it derived revenue from the sale of BREXAFEMME and the development of ibrexafungerp for new indications with GSK." (*Id.*) Plaintiff alleges "it is inconceivable that its employees would not be aware of the FDA's guidance on manufacturing anti-fungal drugs" and cites to FDA guidance for the industry on "Insanitary Conditions at Compounding Facilities" as a specific regulation Scynexis knew it would need to follow. (*Id.* ¶ 58.) Correspondingly, Plaintiff claims Defendants had professed requisite knowledge of these regulations when the company stated it has "[a] drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. We believe we have a team that is capable of managing these activities." (*Id.* ¶ 59.) As further support for scienter, Plaintiff relies on the prior Scynexis's CEO's statement on an earnings call on May 12, 2022, where he called Scynexis a manufacturing business. (*Id.*) Plaintiff also alleges scienter exists because Scynexis admitted it was in control of the drugs. (*Id.* ¶ 60.) Plaintiff contends Scynexis's admission of control comes from an August 14, 2023 statement where the company said its "product revenue, net comprised of sales of BREXAFEMME that [Scynexis] sold as principal given it maintains control of BREXAFEMME product until delivery to its wholesalers at which point control is transferred" as well as from Scynexis claiming "[it] continues to sell BREXAFEMME in the GSK Territory. The Company is the principal for these transactions under ASC 606 as the Company

maintains control of the BREXAFEMME inventory that is then sells to its customers." (*Id.*) Plaintiff finally claims Angulo and Macleod had scienter because they were aware of the details regarding the manufacturing of Scynexis's only drug, and if they were unaware as the CEO and CFO, respectively, such ignorance would constitute "acting in such a deliberately reckless manner as to constitute a fraud and deceit upon Plaintiff and other Class members." (*Id.* ¶ 61.)

D. Procedural History

On November 7, 2023, Plaintiff filed a Class Action Complaint against Defendants for alleged violations of the federal securities laws. (ECF No. 1.) On September 23, 2024, Plaintiff filed an Amended Class Action Complaint ("Amended Complaint") asserting the two causes of action: (1) "Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder" (Count I) against all Defendants, and (2) "Violations of Section 20(a) of the Exchange Act" against Angulo and Macleod (Count II). (ECF No. 14.) On December 20, 2024, Defendants filed a Motion to Dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 8, 9, and 12(b)(6) and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u, *et seq.* ("PSLRA"). (ECF No. 28.) On February 18, 2025, Plaintiff filed an Opposition (ECF No. 29), and, on March 4, 2025, Defendants filed a Reply (ECF No. 30).

II. LEGAL STANDARD

A. Rule 12(b)(6)

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences from the facts alleged in the light most favorable to [the non-moving party]." *Phillips*, 515 F.3d at 228. "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations

omitted). However, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555 (alteration in original) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those "[f]actual allegations must be enough to raise a right to relief above the speculative level[.]" *Twombly*, 550 U.S. at 555 (citations omitted).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). This "plausibility standard" requires the complaint to allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a 'probability requirement.'" *Id.* (citing *Twombly*, 550 U.S. at 556). "[D]etailed factual allegations" are not required, but "more than an unadorned, the-defendant-unlawfully-harmed-me accusation" must be pleaded; it must include "factual enhancement" and not just conclusory statements or a recitation of the elements of a cause of action. *See id.* (citations omitted). In assessing plausibility, the court may not consider any "[f]actual claims and assertions raised by a defendant[.]" *Doe v. Princeton Univ.*, 30 F.4th 335, 345 (3d Cir. 2022).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer

more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (second alteration in original) (quoting Fed. R. Civ. P. 8(a)(2)). Indeed, after *Iqbal*, conclusory or "bare-bones" allegations will no longer survive a motion to dismiss: "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678 (citing *Twombly*, 550 U.S. at 555). To prevent dismissal, all civil complaints must set out "sufficient factual matter" to show that the claim is facially plausible, "allow[ing] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556, 570). The Supreme Court's ruling in *Iqbal* emphasizes that plaintiffs must show that the allegations of their complaints are plausible. *See id.* at 670.

While courts generally may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant to Rule 56]." *See In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any "document *integral to or explicitly relied* upon in the complaint." *In re Burlington*, 114 F.3d at 1426 (quoting *Shaw*, 82 F.3d at 1220). However, "[w]hen the truth of facts in an 'integral' document are contested by the well-pleaded facts of a complaint, the facts in the complaint must prevail." *Princeton Univ.*, 30 F.4th at 342.

B. Heightened Pleading Standard

"[F]aced with a Rule 12(b)(6) motion to dismiss a § 10(b) action, courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." *Institutional Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d

Cir. 2009) (alteration in original) (quoting *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007)). Courts must also "consider the complaint in its entirety, as well as . . . documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Id.* (quoting *Tellabs*, 551 U.S. at 322). However, because this is a securities fraud case, plaintiffs must satisfy the heightened pleading rules codified in the PSLRA. *Id.* The PSLRA replaced Federal Rule of Civil Procedure 9(b) ("Rule 9(b)") "as the applicable pleading standard in private securities class actions." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 242 n.3 (3d Cir. 2013) (citing *Avaya*, 564 F.3d at 253). "Nonetheless, 'Rule 9(b)'s particularity requirement is comparable to and effectively subsumed by the requirements of [15 U.S.C. § 78u–4(b)(1) of] the PSLRA.'" *Id.* (alteration in original) (quoting *Avaya*, 564 F.3d at 253).

Pursuant to Rule 9(b), when alleging fraud, "a party must state with particularity the circumstances constituting fraud or mistake, although 'intent, knowledge, and other conditions of a person's mind may be alleged generally.'" *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 249 (3d Cir. 2017) (quoting Fed. R. Civ. P. 9(b)); *see also United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (holding that a "plaintiff alleging fraud must . . . support its allegations with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue" (citation omitted)). Accordingly, "a party must plead [its] claim with enough particularity to place defendants on notice of the 'precise misconduct with which they are charged.'" *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 502 (3d Cir. 2017) (citation omitted).

Likewise, "[u]nder the PSLRA's heightened pleading instructions, any private securities complaint alleging that the defendant made a false or misleading statement must: (1) 'specify each

statement alleged to have been misleading [and] the reason or reasons why the statement is misleading'"; and (2) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Tellabs*, 551 U.S. at 321 (alteration in original) (quoting 15 U.S.C. §§ 78u-4(b)(1), (b)(2)). Therefore, the PSLRA "requires that a complaint 'state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, i.e., the defendant's intention "to deceive, manipulate, or defraud."'" *Rahman*, 736 F.3d at 241–42 (quoting *Tellabs*, 551 U.S. at 313).

"To plead falsity, Rule 9(b) and the PSLRA each demand specificity." *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 680 (3d Cir. 2023). "Rule 9(b) requires that a fraud plaintiff "state with particularity the circumstances constituting fraud[,]" *i.e.*, "the time, place, and contents of the false representations or omissions, as well as the identity of the person making the statement and the basis for the statement's falsity." *Id.* "Like Rule 9(b), the PSLRA requires the pleadings to identify 'each statement alleged to have been misleading' and to specify 'the reason or reasons why the statement is misleading.'" *Id.* (quoting 15 U.S.C. § 78u-4(b)(1)). "And if allegations of falsity are based on information and belief, instead of on 'evidentiary support,' . . . the PSLRA requires the complaint to plead, with particularity, facts 'sufficient to support a reasonable belief as to the misleading nature of the statement or omission' before the allegations can be accepted as true." *Id.* (citing Fed. R. Civ. P. 11(b)(3); *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004) (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 n.1 (2d Cir. 2000))). To satisfy this particularity requirement, the plaintiff must plead "facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could

draw from the facts alleged." *Tellabs*, 551 U.S. at 324. "Upon a motion by any defendant, a claim for securities fraud under § 10(b) and Rule 10b-5 that lacks particularized allegations of falsity must be dismissed." *City of Warren Police*, 70 F.4th at 681.

"Although the pleading standards in Rule 9(b) and the PSLRA can be generally reconciled harmoniously for allegations of falsity, the PSLRA's requirements for allegations of *scienter* control over the more lenient standard in Rule 9(b) for mental-state allegations." *Id.* at 681 n.1 (citing *Avaya*, 564 F.3d at 253 ("The PSLRA's requirement for pleading scienter . . . marks a sharp break with Rule 9(b).")); *Tellabs*, 551 U.S. at 323–24); *compare* Fed. R. Civ. P. 9(b) (permitting "[m]alice, intent, knowledge, and other conditions of a person's mind [to] be alleged generally"), *with* 15 U.S.C. § 78u-4(b)(2)(A) (requiring a particularized statement of the "facts giving rise to a strong inference that the defendant acted with the required state of mind").

C. PSLRA Safe Harbor

The PSLRA's safe harbor provision "immunizes from liability any forward-looking statement, provided that: the statement is identified as such and accompanied by meaningful cautionary language; or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood." *Avaya*, 564 F.3d at 254 (citing 15 U.S.C. § 78u-5(c)).

> The term "forward-looking statement" is broadly defined in the statute to include statements "containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items"; statements of "the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer"; or statements of "future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission." 15 U.S.C. § 78u-5 (i)(1)(A)-(C). Further, forward-looking statements include "any statement of the assumptions underlying or relating to any statement described" in the definition. § 78u-5(i)(1)(D).

Id. at 255. Mixed present and future statements are entitled to the safe harbor only as to the portion of the statement that refers to the future. *Id.* Additionally, to be protected under the PSLRA safe harbor, the forward-looking statements must be accompanied by "extensive and specific" cautionary language. *Id.* at 256 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004)). "[A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge." *Id.* (quoting *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000)).

III. DECISION

The Court first addresses whether Plaintiff has sufficiently alleged Section 10(b) and Rule 10b-5 violations against the Defendants and then addresses whether Plaintiff has sufficiently alleged a Section 20(a) violation against Angulo and Macleod.

A. Defendants' Motion to Dismiss Plaintiffs' Section 10(b) and 10b-5 Claims (Count I of the Amended Complaint)

Defendants argue Plaintiffs' Amended Complaint should be dismissed for failure to state a claim under Section 10(b) of the Exchange Act. (*See generally* ECF Nos. 28, 28-1.) They state, "Plaintiff's theory that Defendants misled investors by making statements in March and May 2023 about its vendors' manufacturing 'capabilities,' while not disclosing a cross-contamination risk that prompted a voluntary recall four months later, fails to adequately allege a false or misleading statement for a number of independent reasons." (*Id.* at 14.) Specifically, Defendants contend: (1) Plaintiff fails to plead particularized facts showing Scynexis was aware of any cross-contamination risk when any alleged false or misleading statement was made; (2) Plaintiff fails to

plead particularized facts showing Scynexis did not ensure cGMP compliance; (3) Scynexis disclosed the overarching risk Plaintiff claims it concealed; (4) none of the challenged statements triggered a duty to disclose that third party manufacturing equipment was used to produce a non-antibacterial beta lactam; (5) the challenged statements are inactionable as a matter of law; and (6) the complaint should be dismissed because plaintiff fails to plead particularized facts giving rise to a strong inference of scienter. (*Id.* at 14–25.) Defendants also submit that because Plaintiff has not sufficiently pled a Section 10(b) claim, the Section 20(a) claim against Angulo and Macleod fails. (*Id.* at 29.)

In opposition, Plaintiff argues Defendants' Motion should be denied because he has adequately alleged actionable misrepresentations and omissions that were false and misleading, material, and were not opinions or puffery. (ECF No. 29 at 20–26.) Plaintiff also claims Defendants had a duty to disclose that Scynexis's manufactures were not in compliance with appropriate requirements and Scynexis was failing to monitor and ensure such compliance. (*Id.* at 26.) Finally, Plaintiff states the Amended Complaint raises a strong inference of scienter and it adequately alleges control person liability. (*Id.* at 28, 33.)

In reply, Defendants argue again Plaintiff fails to adequately plead falsity. (*See generally* ECF No. 30.) Specifically, Defendants maintain that: (1) Plaintiff alleges no particularized facts which demonstrate Scynexis was aware of any cross-contamination risk when any challenged statement was made; (2) Plaintiff fails to adequately plead Defendants made false or misleading statement despite not being aware of any cross-contamination risk; (3) Scynexis disclosed the overarching risk Plaintiff claims it concealed; (4) none of the statements challenged triggered a duty to disclose that manufacturing equipment was used to produce a non-antibacterial beta lactam; (5) the challenged statements are inactionable as a matter of law; and (6) Plaintiff fails to plead

particularized facts giving rise to a strong inference of scienter. (*Id.* at 7–18.)

"The private right of action under Section 10(b) and Rule 10b–5 . . . creates liability for false or misleading statements or omissions of material fact that affect trading on the secondary market." *In re Burlington*, 114 F.3d at 1417. To state a claim for securities fraud pursuant to Section 10(b) of the Exchange Act, "plaintiffs must allege (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014) (citations omitted). "To prevail on a § 10(b) claim, a plaintiff must show that the defendant made a misleading statement or omission as to a material fact." *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516, 537 (W.D. Pa. 2019) (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011)). "[A] fact or omission is material only if 'there is a substantial likelihood that it would have been viewed by the reasonable investor as having significantly altered the "total mix" of information' available to the investor." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002) (quoting *Levinson*, 485 U.S. at 231–32). "[W]hen a stock is traded in an efficient market, the materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm's stock." *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000). "Because in an efficient market 'the concept of materiality translates into information that alters the price of the firm's stock,' if a company's disclosure of information has no effect on stock prices, 'it follows that the information disclosed . . . was immaterial as a matter of law.'" *Id.* (quoting *In re Burlington*, 114 F.3d at 1425). However, "vague and general statements of optimism 'constitute no more than "puffery" and are understood by reasonable investors as such.'" *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999) (quoting *In re Burlington*,

114 F.3d at 1428 n.14). "A statement is considered puffery only when it is immaterial." *Enzymotec*, 2015 WL 8784065, at *14. An opinion "is misleading if it: (i) was not sincerely believed when made; (ii) contains an expressly embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits appropriate qualifying language." *City of Warren Police*, 70 F.4th at 686.

Likewise, to state a claim for securities fraud under Rule 10b–5, a plaintiff "must 'allege defendants made a misstatement or an omission of material fact with scienter in connection with the purchase or the sale of a security upon which plaintiffs reasonably relied and plaintiff's [sic] reliance was the proximate cause of their injury.'" *Avaya*, 564 F.3d at 251 (quoting *Winer Family Tr. v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007)). However, "Section 10(b) and Rule 10b–5 'do not create an affirmative duty to disclose any and all material information.'" *Edinburgh Council*, 754 F.3d at 174 (quoting *Matrixx Initiatives*, 563 U.S. at 44). "Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* (alterations in original) (quoting *Matrixx Initiatives*, 563 U.S. at 44). "Silence, absent a duty to disclose, is not misleading under Rule 10b–5." *Id.* (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988)).

To satisfy the heightened pleading standard in a securities-fraud case, "media sources must be sufficiently detailed to indicate [] their reliability and be based on an independent investigative effort." *In re Mylan N.V. Sec. Litig.*, Civ. A. No. 20-00955, 2023 WL 3539371, at *6 (W.D. Pa. May 18, 2023) (alteration in original) (quoting *In re Loewen Grp. Inc. Sec. Litig.*, Civ. A. No. 98-06740, 2004 WL 1853137, at *6 (E.D. Pa. Aug. 18, 2004)); *see In re Optionable Sec. Litig.*, 577 F. Supp. 2d 681, 690 (S.D.N.Y. 2008) ("[N]ewspaper articles should be credited only to the extent that other factual allegations would be—if they are sufficiently particular and detailed to indicate their reliability. Conclusory allegations of wrongdoing are no more sufficient if they come

from a newspaper article than from plaintiff's counsel." (citation and internal quotation marks omitted)). Generally, when considering confidential witness allegations, it is proper to "evaluat[e] the 'detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.'" *Avaya*, 564 F.3d at 263 (quoting *Chubb Corp.*, 394 F.3d at 147).

Here, the Court finds the Amended Complaint fails to satisfy the heightened pleading requirements of Rule 9(b) and the PSLRA because, even accepting the Amended Complaint's factual allegations as true, it does not sufficiently allege a material misrepresentation or omission by Defendants. Plaintiff has not adequately alleged material misstatements or omissions because he has not alleged with sufficient particularity how Defendants' statements—regarding their then-current beliefs about following all applicable FDA regulations, having quality assurance systems or proper controls in place for compliance, and any other pertinent factors relating to the equipment used to manufacture the drug not being sufficiently separated to prevent a risk of cross-contamination—were false or otherwise misleading at the time they were made. Plaintiff does not allege any internal and/or contradictory information undercutting Defendants' belief that they and any third-party contractor was compliant with cGMP beyond an argument of fraud by hindsight when alleging GSK was able to "quickly uncover[] that Scynexis was not complying with current Good Manufacturing Practices, resulting in a recall and the cratering of the Company's stock." (ECF No. 14 at 17.) *See City of Warren Police*, 70 F.4th at 693 ("[T]he PSLRA forbids reliance on 'speculative fraud by hindsight' allegations") (quoting *In re Rockefeller Center Properties, Inc. Sec. Litig.*, 311 F.3d 198, 225 (3rd. Cir. 2002)); *Williams v. Globus Med.*, Inc., 869 F.3d 235, 244 (3d Cir. 2017) (stating factual allegations "cannot rely exclusively on hindsight, but must be

sufficient to show that the challenged statements were actionably unsound when made"); *In re PayPal Holdings Inc. Sec. Litig.*, 2025 WL 325603, at *17 (D.N.J. Jan. 29, 2025) at *15 ("[A] purported claim of securities fraud based merely on information that became apparent after the fact, with no indication that the speaker was aware, or at least should have been aware of the information at the time of his earlier statement, is the exact type of 'fraud by hindsight' argument that the Third Circuit has long rejected as improper.") (citing *Tanaskovic v. Realogy Holdings Corp.*, Civ. A. No. 19-15053, 2021 WL 211049, at *6 (D.N.J. Jan. 21, 2021)); *Lewakowski v. Aquestive Therapeutics, Inc.*, Civ. A. No. 21-3751, 2023 WL 2496504, at *12 (D.N.J. Mar. 14, 2023) ("The Third Circuit has deemed Plaintiffs' bald assertions that Defendants 'must have known' an impermissible attempt to plead fraud by hindsight.") (citing *Chubb Corp.*, 394 F.3d at 158); *In re Electronics for Imaging Inc. Sec. Litig.*, Civ. A. No. 17-5992, 2019 WL 397981 at *8 (D.N.J. Jan. 31, 2019) ("The Complaint alleges absolutely no corroborative facts—let alone 'strong circumstantial evidence'—to support the inference that Defendants lied about the performance or the depth of their review. As such, this allegation amounts to nothing more than pure conjecture."); *see also Keystone Assocs. LLC v. Barclays Bank PLC*, Civ. A. No. 19-00796, 2020 WL 109008, at *3 (D. Del. Jan. 9, 2020) ("To be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events.") (quoting *In re NAHC*, 306 F.3d at 1330); *In re Aceto Corp. Sec. Litig.*, Civ. A. No. 18-2425, 2019 WL 3606745 at *4 (E.D.N.Y. 2019) (describing the assumption "that because a problem [with internal controls] was disclosed in November, defendants must have known of the problem in August" as "a classic example of 'fraud by hindsight' insufficient to support a 10(b) claim" (citing *Novak*, 216 F.3d at 309)). Plaintiff has also not adequately alleged facts showing this opinion "(i) was not sincerely believed when made; (ii) contains an expressly

embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits appropriate qualifying language." *City of Warren Police*, 70 F.4th at 686.

Defendants correctly point out the Amended Complaint "contains no well-pled factual allegations . . . . Rather, Plaintiff's entire theory of fraud assumes, absent any concrete allegations, that the 'risk' existed at the beginning of the Class Period, i.e., March 2023, and that each Defendant knew about it at that time." (ECF No. 28-1 at 15.) Likewise, Defendants contend "there are no factual allegations about when the third-party manufacturing vendor first used the facility to produce non-antibacterial beta lactams, when BREXAFEMME was manufactured in relation to any such production, or whether, let alone when, any Defendant learned of the risk of beta lactam cross-contamination." (*Id.*) Plaintiff claims "GSK was quickly able to uncover the issues by inspecting the facility," as the basis for the allegation of fraud, however, he provides no documentation or interview with an employee that demonstrates any such issue was discovered sooner than when Scynexis announced the problem and that it would conduct a recall, which occurred six months after the licensing agreement was announced. (*See* ECF No. 29 at 31.) Instead, the only support he provides is a third-party analyst's statement that "[w]e would expect that ahead of GSK's March licensing agreement it would have physically inspected the IBX manufacturing facilities" and the general claim that Defendants' expertise and experience leads to the logical inference of recklessness to the point of fraud if the issue was truly not known to the Defendants. (ECF No. 14 ¶¶ 10, 63–64.) Likewise, neither the analyst statement provided nor the Plaintiff elsewhere in the Amended Complaint explains how the discovery of the potential cross-contamination was quick. While "any information that sheds light on whether class period statements were false or materially misleading is relevant" when reviewing allegations for the inference of falsity, the analyst's statement alone is not enough to support the conclusory statement

that Defendants were aware at all times of the alleged potential for cross-contamination under the heightened pleading standard. *See In re Merck & Co., Sec. Litig.*, 432 F.3d 261, 272; *see also In re BioLineRx Ltd. Sec. Litig.*, Civ. A. No. 23-00041, 2024 WL 3409800, at *10 (D.N.J. July 15, 2024) ("[A]n implied assumption without adequate supporting underlying facts is insufficient to satisfy the heightened pleading standards for a case alleging violations of Section 10(b) and Rule 10b-5."); *Paxton v. Provention Bio, Inc.,* Civ. A. No. 21-11613, 2022 WL 3098236, at *14 (D.N.J. Aug. 4, 2022) ("Fatally, the [Amended Complaint] makes no further factual allegations concerning when the Company learned of these [alleged risks].") (citing *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 967 (D. Md. 1995) (rejecting allegation of securities fraud when "Plaintiffs ha[d] pleaded no specific facts to show why Defendants knew or should have known [something] to be a problem")).

Although Plaintiff claims he "is not required to plead facts that can only be attained through discovery," (ECF No. 29 at 31; *see also id.* at 10), "[p]leading 'true facts' generally requires that the plaintiff 'cit[e] contemporaneous sources' rather than rely on 'conjecture based on subsequent events,'" which is "traditionally done by relying on confidential witnesses or documentary evidence such as internal memoranda to establish the reason(s) why the statement or omission was false or misleading at the time it was made." *In re Ocugen, Inc. Sec. Litig.*, 659 F. Supp. 3d 572, 589–90 (E.D. Pa. 2023), *aff'd*, Civ. A. No. 23-1570, 2024 WL 1209513 (3d Cir. Mar. 21, 2024) (citing *Williams*, 869 F.3d at 244; *Chubb Corp.*, 394 F.3d at 145). As it stands, Plaintiff's Amended Complaint "does not rely upon internal documents or confidential witnesses to establish true facts that conflict with Defendants' statements at issue." *Id.* at 590. Likewise, "an omission 'that is misleading only in hindsight' cannot form the basis for a securities fraud claim*." In re Discovery Lab'ys Sec. Litig.*, Civ. A. No. 06-1820, 2006 WL 3227767, at *9 (E.D. Pa. Nov. 1, 2006) (citing

Zucker v. Quasha, 891 F. Supp. 1010, 1017 (D.N.J. 1995), *aff'd*, 82 F.3d 408 (3d Cir. 1996)). Similarly, the claim cannot be supported "merely by means of conclusory assertions." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 194 (2015). On the facts pled, there is no basis for the Court to conclude Defendants made false statements without relying upon hindsight, because the allegation is only "speculative conclusion, accompanied by no additional explanation or supporting facts." *Connor v. Unisys Corp.*, Civ. A. No. 22-4529, 2024 WL 387633, at *8 (E.D. Pa. Feb. 1, 2024). Although "'later developments may allow a reasonable inference that prior statements were untrue or misleading when made,' *City of Warren Police*, 70 F.4th at 693, the Court 'cannot credit factual allegations, such as this, which do not rise above the speculative level.'" *Id.* Without providing this Court with further information regarding the allegations that Scynexis's manufacturers were not in compliance with appropriate requirements and Scynexis was failing to monitor and ensure such compliance, Plaintiff's claim is merely conclusory and insufficient.

Accordingly, Defendants' Motion to Dismiss Count I of the Amended Complaint is **GRANTED**. Because the Court finds the Amended Complaint does not sufficiently allege with particularity a material misrepresentation or omission made by Defendants, it concludes that further analysis of the Amended Complaint is unnecessary at this time. *See Osio v. DeMane*, Civ. A. No. 05-02283, 2006 WL 2129460, at *12 (D.N.J. June 20, 2006) (noting "the Court need not address the remaining elements or pleading requirements of a claim under § 10(b) or Rule 10b-5" because plaintiffs did not sufficiently plead an omission of material fact).

B. Defendants' Motion to Dismiss Plaintiff's Section 20(a) Claim Against Angulo and Macleod (Count II)

Section 20(a) provides:

> Every person who, directly or indirectly, controls any person liable

> under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). Liability under Section 20(a) "is derivative of an underlying violation of Section 10(b) by the controlled person." *Rahman*, 736 F.3d at 247 (quoting *Avaya*, 564 F.3d at 252). "Thus, for a controlling person to be liable, the person over whom control was exercised must have committed a primary violation of the securities laws." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 280 (D.N.J. 2007) (citations omitted).

Here, because the Court found the Amended Complaint fails to state a claim under Section 10(b), and liability under Section 20(a) is derivative of an underlying Section 10(b) violation, the Court finds the Amended Complaint also fails to state a claim under Section 20(a) against Angulo and Macleod. *See Biondolillo v. Roche Holding AG*, Civ. A. No. 17-04056, 2019 WL 1468140, at *4 (D.N.J. Apr. 3, 2019) ("Because the Second Amended Complaint fails to state a claim under Section 10(b), it also fails to state a claim under Sections 20(a) and 20A.").

Therefore, Defendants' Motion to Dismiss Count II of the Amended Complaint is **GRANTED**.

C. Leave to Amend

Defendants request Plaintiff's Amended Complaint be dismissed with prejudice. (ECF No. 28-1 at 29.) However, the Federal Rules of Civil Procedure generally require the Court to "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15. "In the Third Circuit, plaintiffs whose complaints fail to state a cause of action are entitled to amend their complaint unless doing so would be inequitable or futile." *Lovallo v. Pacira Pharms., Inc.*, Civ. A. No. 14-06172, 2015 WL 7300492, at *14 (citing *Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d

247, 252 (3d Cir. 2007)).

Here, allowing Plaintiff to amend would not be futile as he could provide additional factual content to attempt to cure the deficiencies in the Amended Complaint. *See Munenzon v. Peter Advisors, LLC*, 553 F. Supp. 3d 187, 210 (D.N.J. 2021); *see also United States ex rel. Petratos v. Genentech, Inc.*, Civ. A. No. 11-03691, 2014 WL 7331945, at *2 (D.N.J. Dec. 18, 2014) (stating that "within the Third Circuit, even when a complaint is vulnerable to Rule 12(b)(6) dismissal, the district court should allow the party a curative amendment, unless the amendment would be futile or inequitable").

Therefore, the Court denies Defendants' request to dismiss the Amended Complaint with prejudice and grants Plaintiff leave to file a second amended complaint.

IV. CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss (ECF No. 28) is **GRANTED**, and Plaintiff's Amended Complaint (ECF No. 14) is **DISMISSED WITHOUT PREJUDICE**. An appropriate Order follows.

Dated: July 30, 2025

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE